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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,599	04/12/2004	Thomas R. Keyer	8932-927-999	3549
51832	7590	11/26/2007		
JONES DAY 222 EAST 41ST STREET NEW YORK, NY 10017-6702			EXAMINER SHAFFER, RICHARD R	
			ART UNIT 3733	PAPER NUMBER
			MAIL DATE 11/26/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/822,599	<b>Applicant(s)</b> KEYER ET AL.	
	<b>Examiner</b> Richard R. Shaffer	<b>Art Unit</b> 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 September 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-13, 15, 16, 20-32, 34-51 and 55-76 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13, 15, 16, 20-32, 34-51 and 55-76 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Allowable Subject Matter*

The indicated allowability of claims 14, 19, 20, 38, 43, 44, 51 and 55-76 is withdrawn in view of the newly discovered reference(s) to Roethal (US Patent Application Publication 2002/0139423). Rejections based on the newly cited reference(s) follow.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13, 15 and 21-26 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 recites the limitation, "the first and second tips being sized and configured to **slide** onto ..." The disclosure as originally filed does not support specific language as to how the snap-on feature works. While there are snap-on connections that can slide over and then click, not all function in this manner. Therefore, there is no inherency that a snap-on engagement slides causing the claim to contain new matter not previously disclosed. All dependent claims are rejected for containing the new matter limitation.

Claims 69 and 70 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 69 recites "further include a tip sized and configured to snap onto..." Claim 66 already sets forth a first and second tip sized and configured to snap onto. Applicant therefore has added additional limitation to which the specification does not support thereby not enabling one of ordinary skill in the art to make and/or use the device.

Claim 70 is rejected for being dependent upon a non-enabled base claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-12, 15, 21-23, 27-32, 34-36, 39-41, and 45-47 are rejected under 35 U.S.C. 102(e) as being anticipated by Markworth et al (US Patent 6,660,006).

Markworth et al disclose a system (**Figure 6B**) comprising: a holder assembly (**200**) having a plurality of fingers (**206**) pointing radially inward at a distal end for engaging a spinal implant body (**104**); a release assembly (**300 and 400**) made of a pusher member (**400**) and a tubular member (**300**); the tubular member slidably disposed (partially) within the holder assembly (**200**); the pusher member (**400**) sized to slidably surround (coaxially accept) a portion of the holder assembly (**200**); the pusher (**400**) having a recess at the left most portion of **404** for engaging a longitudinal spinal rod (**114**); the fingers (**206**) define a U-shaped recess configured to correspond with the recess formed in the pusher member to allow the spinal rod to extend completely through the holder assembly and pusher member; the fingers (**206**) engage recesses (**105**) of the spinal implant; an actuating system with a first grip (**514**), second grip (**218**), a first jaw member (one of many **704**), a second jaw member (another one of many **704**) and first and second tips (**502**); the distal end of the tubular member (**300**) includes a hole (**308**) to correspond with a hole (**412**) on the pusher in order to receive a pin (**112**); the tubular member (**300**) also being sized to accept the spinal implant body (**104**) within; the proximal end of the holder assembly (**200**) has a slot (**222**) to accept a portion of the actuating member; the tubular member (**300**) having a pair of slots (**306** – on both sides) to also receive a portion of the actuating member, the slots facilitate proper alignment of the tubular member within the holder assembly; the first grip member (**514**) is pivotally coupled to the first jaw member (**704**); the second grip member (**218**) is pivotally coupled to the second jaw member (another **704**); the spinal implant having a fastener (**120**); a cylindrical body (**104**); and an anchor member

(unlabeled) with a curvate head (inherent when considering **Figure 1D** with **Figure 1E**) that fits within the cylindrical body.

In regard to the new limitation in claim 1 reciting the tips (502) "configured to slide onto and engage the holder and release assemblies", the tips (502) inherently are slid over and then engaged to assemble the device originally.

Claims 1 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Beale et al (US Patent 6,440,133).

Beale et al disclose a device comprising:

**[First Interpretation]** a holder assembly (100); a release assembly (80 and 500); an actuating member (52, 54, 130, 140, 120, and 122); the release assembly comprising a tubular member (80) disposed within holder (100) and a pusher member (500) disposed about (Column 7, Lines 1-37) holder (100); a proximal end of the holder assembly (100) has a slot (110a) to receive a portion of the actuating member; the tubular member (80) has a pair of slots (91) to correspond with a pair of slots (114) in the holder assembly (100); the actuating member which is orientated perpendicular (see **Figure 5**) to the longitudinal axes of the holder and release assemblies has a first hand grip (54), a second hand grip (52), a first jaw member (120 and 130), and a second jaw member (122 and 140); the first grip (54) and first jaw (120 and 130) are pivotally coupled; the second grip (52) and second jaw (122 and 140) are also pivotally coupled; pins (139, 149) connect the first grip (54) to the second jaw (122 and 140) member and the second grip (52) to the first jaw member (120 and 130). The device further has first

(either hole 128 or 120 or corresponding hole on 122) and second (either 146a or 136b) tips to slidably engage the holder and release assemblies.

**[Second Interpretation]** a holder assembly (80) having a pair of fingers (94, 96) having inward pointing ledges (94f, 94e, 96f, 96c); a release assembly (100); an actuating assembly (52, 54, 130, 140, 120, and 122); the proximal end of the holder assembly (80) having a slot (98a) to connect with a portion of the actuating member; the release assembly (100) having a proximal pair of slots (118, 119) to connect with a portion of the actuating member; the actuating member which is orientated perpendicular (see Figure 5) to the longitudinal axes of the holder and release assemblies has a first hand grip (54), a second hand grip (52), a first jaw member (120 and 130), and a second jaw member (122 and 140); the first grip (54) and first jaw (130) are pivotally coupled; the second grip (52) and second jaw (122 and 140) are also pivotally coupled; pins (139, 149) connect the first grip (54) to the second jaw (122 and 140) member and the second grip (52) to the first jaw member (120 and 130). The device further has first (either hole 128 or 120 or corresponding hole on 122) and second (either 146a or 136b) tips to slidably engage the holder and release assemblies.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 24-26 and 48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Markworth et al in view of Errico et al (US Patent 5,688,274).

Markworth et al disclose all of the claimed limitations except for a spinal implant with an external collar to compress the spinal implant body about the head of the bone anchor. Errico et al teach (**Column 5, Lines 1-65, Figure 21**) a bone anchor using a polyaxial head enclosed by a compressible body (208) and locked by a collar (250). The benefit of such an arrangement is to allow for ease of surgery. It allows the surgeon to easily implant components with minimal concern that improper alignment will occur. First the bone anchor can be placed in the subject, then the body member placed atop the bone anchor. Then a spinal rod placed within cavity (224) and the entire device repositioned until the desired alignment is achieved and finally fixed in place. It would have been obvious as a matter of design choice to one having ordinary skill in the art at the time the invention was made to have used a compressible body with a collar in the device of Markworth et al as a means to provide a surgeon an easily implantable yet stable spinal system.

Claims 38 and 65-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Markworth et al in view of Roethal (US Patent Application Publication 2002/0139423).

Markworth et al disclose all of the claimed limitations except for the first and second tips configured to snap onto and engage the holder and release assemblies. Roethal teaches (**Page 3, Paragraph 0028**) that suitable and equivalent connection



means includes friction fit, snap-fit, threaded connection, adhesive connection or the like. It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the threaded connection of Markworth et al for a snap-fit connection in order to provide for a quick fixation (such as for interchangeability and ease of cleaning) with predictable results.

Claims 12, 13, 16, 20, 27, 35-37, 40-44, 51, 55-64 and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beale et al in view of Roethal.

Beale et al disclose all of the claimed limitations except for the tubular member (80 from first interpretation) having a pair of slots configured to receive a portion of the actuating member and the first and second tips having a snap-on engagement.

In **Figure 13**, an actuating portion it engages is shown having two slots (136b) through which the protrusion (98) passes. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the tubular member (80) with two slots and the actuating portion from **Figure 13** with a protrusion since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. *In re Einstein*, 8 USPQ 167.

Roethal teaches (**Page 3, Paragraph 0028**) that suitable and equivalent connection means includes friction fit, snap-fit, threaded connection, adhesive connection or the like. It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the connections of Beale et al for a snap-fit connection in order to provide for a quick fixation (such as for interchangeability and ease of cleaning) with predictable results.

Claims 72-74 rejected under 35 U.S.C. 103(a) as being unpatentable over Beale et al in view of Roethal and in further view of Markworth et al and Errico et al.

The combination of Beale et al and Roethal disclose and teach all of the claimed limitations except for a polyaxial bone anchor with a compressible body and a collar to compress the recess about the head. As discussed previously, Markworth et al and Errico et al disclose a polyaxial screw system with a collar compressing the body about the head. It would have been obvious to one having ordinary skill in the art at the time of invention to substitute the structure as taught by Markworth et al and Errico et al to provide for a spinal rod anchoring system with predictable results.

Applicant's arguments with respect to claims 1-13, 15, 16, 20-26, 51 and 55-76 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments with respect to claims 27-32 and 34-50 filed September 17<sup>th</sup>, 2007 have been fully considered but they are not persuasive.

Applicant contends that Markworth et al and Beale et al both fail to disclose "the at least one hole and the at least one aperture being **sized and configured to receive** at least one pin for securing the pusher member to the tubular member, the pin being sized and configured to be displaceable within the elongated slot of holding assembly..." The limitation "sized and configured to receive" recites an intended use. recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

**Conclusion**

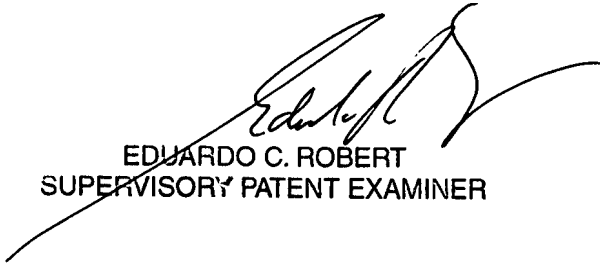
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard R. Shaffer whose telephone number is 571-272-8683. The examiner can normally be reached on Monday-Friday (7am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Richard Shaffer  
November 19<sup>th</sup>, 2007



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